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EXAMINER

DESANTO, MATTHEW F

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 06/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/578,317

Applicant(s)

SHKOLNIK, BORIS

Examiner

Matthew F DeSanto

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, are drawn to balloon catheter, classified in class 604, subclass 96.01.

II. Claim 17, is drawn to method of purging air, classified in class 128, subclass 898.

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case invention I can be used to perfuse fluid into an organ or blood vessel.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Henry Collins on 4/23/02 a provisional election was made with traverse to prosecute the invention of I, claims 1-16. Affirmation of this election must be made by applicant in replying to this Office action. Claim 17 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Burns et al. (USPN 5176698), discloses a balloon catheter with a catheter body comprising at least one tubular member having a tubular wall (ref #. 29) and having a lumen extending throughout the length of the tubular member (ref #. 24), the tubular member further having a proximal end and a distal end, an inflatable balloon (ref #. 16) having a main body portion, a proximal portion, and a distal portion, the proximal portion and the distal portion extending from the main body portion, the distal portion of the balloon being bonded to the tubular member near the distal end of the tubular member and the proximal portion of the balloon being bonded to the tubular member proximal to the distal portion of the balloon, where the balloon is made of polyolefin, further comprising

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a coupling member (ref #. 12) having a lumen extending therethrough, the coupling member being mounted on the proximal end of the tubular member and the lumen of the coupling member communicating with the lumen of the tubular member, and a syringe coupled to the coupling member for applying a liquid within the lumen of the tubular member at a fluid pressure is exerted between 20 psi and 45 psi, and at least one aperture (ref # 28) for purging air from the lumen of the catheter body, the aperture extending radially through the wall of the tubular member at a point proximal to the proximal portion of the inflatable balloon. (Figures 1, 6,9 and Columns 3 lines 50-60, Col. 4, lines 11-20, Col. 5, lines 10-42).

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burns et al. as applied to claim 11 above, and further in view of Rydell (USPN 4811737), and further in view of Carlblom (USPN 5637365), and further in view of Follmer et al. (USPN 5728065).

9. Burns et al. discloses a balloon catheter with a catheter body comprising at least one tubular member having a tubular wall (ref #. 29) and having a lumen extending throughout the length of the tubular member (ref #. 24), the tubular member further having a proximal end and a distal end, an inflatable balloon (ref #. 16) having a main

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body portion, a proximal portion, and a distal portion, the proximal portion and the distal portion extending from the main body portion, the distal portion of the balloon being bonded to the tubular member near the distal end of the tubular member and the proximal portion of the balloon being bonded to the tubular member proximal to the distal portion of the balloon, where the balloon is made of polyolefin, further comprising a coupling member (ref #. 12) having a lumen extending therethrough, the coupling member being mounted on the proximal end of the tubular member and the lumen of the coupling member communicating with the lumen of the tubular member, and a syringe coupled to the coupling member for applying a liquid within the lumen of the tubular member at a fluid pressure is exerted between 20 psi and 45 psi, and at least one aperture (ref # 28) for purging air from the lumen of the catheter body, the aperture extending radially through the wall of the tubular member at a point proximal to the proximal portion of the inflatable balloon. (Figures 1, 6,9 and Columns 3 lines 50-60, Col. 4, lines 11-20, Col. 5, lines 10-42), but fails to disclose the specific size of the apertures, and placing the balloon in a protective tube.

10. Rydell discloses the specific size of venting ports in a balloon catheter, where the size of the hole is between 0.0005 to 0.0015 inches. (Column 3, lines 22-37 and Column 4, lines 10-24).

11. Carlblom discloses that polyolefin is a "gas-permeable material." Column 10, lines 18-49.

12. Follmer et al. discloses the use of a constraining member (ref #. 200), to be placed over the inflatable balloon

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13. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the size of the aperture in the catheter of Rydell and to make the inflatable balloon out of a gas permeable material by Carlblom and to place the balloon in a constraining member taught by Follmer et al. with the invention of Burns et al.

14. The suggestion/motivation for making the apertures 0.0005 to 0.0015 is because this size would have been able to permit air to be vented and preclude the outflow of liquid as well as prevent the inflow of air back in the catheter as taught by Rydell col. 4, lines 10-24, while the motivation for making the balloon out of a gas permeable material is taught by Burns et al. and further supported by Carlblom col. 10, lines 18-40, where Carlblom teaches that polyolefin is a polymer that is gas permeable, and polyolefin is the material that Burns et al. uses in his invention, and the motivation for the protective tube or constraining member was to limit the radial expansion of the balloon but at the same time expanding the balloon allowing for a greater rate of gas and liquid to be flushed out of the vent hole, under normal inflation pressure (Follmer et al. column 7, line 45-column 8, line 14).

15. Therefore, it would have been obvious to combine Burns et al. with Rydell and with Carlblom and with Follmer et al. to obtain the invention as specified in claim 1-16.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 8:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1-703-308-0858.

Matthew DeSanto  
Art Unit 3763  
June 3, 2002

  
ANH TUAN T. NGUYEN  
PRIMARY EXAMINER

6/3/02